THE FEMALE HEALTH COMPANY

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August 30, 1999

Dockets Management Brand
(HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

RE: Docket No. 99N-1309
Proposed Classification of Female Condom

Dear Sir or Madam:

These comments are being submitted on behalf of The Female Health Company (FHC) which sells the *Reality*® brand of female condom in the United States and elsewhere. *Reality*® is the only female condom that has been approved for distribution by the U.S. Food and Drug Administration following submission of a Premarket Approval Application (PMA).

In 1989, the Wisconsin Pharmacal Company (WPC) (the predecessor to FHC) participated in the FDA's Obstetrics-Gynecology Devices Panel (the Panel) meeting that discussed premarket testing requirements for female condoms. Many of the recommendations of the Panel reflected studies already conducted by WPC. Following that meeting, WPC conducted other studies in accordance with the recommended guidelines agreed by the 1989 Panel. To our knowledge, *Reality*® is the only female condom that has been fully tested in accordance with these guidelines. Since introducing *Reality*® in the U.S., the safety and effectiveness of the *Reality*® brand of female condom has been demonstrated by additional and extensive in vitro and in vivo testing both here in the U.S. and around the world.

FHC believes that the Panel's recommendations for premarket testing of female condoms continue to be appropriate. Female condoms, unlike male condoms, can differ significantly in design and materials. These differences could have profound effects on factors that affect safety and efficacy e.g., dislodgment, displacement, bursting and tearing. Weaknesses in material can lead to leakage of seminal fluids. Standard leak tests may be inappropriate. Because the proper method for insertion and use of a female condom may not be obvious, clear directions for use are essential. In short, all of these factors require appropriate testing, each specific to the product's design and materials.

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To ensure that any new female condom is safe and effective, FHC endorses FDA's proposed requirement that female condoms be classified as a Class III device that requires submission and FDA approval of a PMA.

Sincerely,

Mary Ann Leeper, Ph.D.
President and COO

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